Pharmacy Regulation

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Affiliate Professor, UW School of Pharmacy
Objectives

- Describe Pharmacy regulation process
- Describe who may prescribe drugs in WA
- Describe Drug Classifications
- Describe Drug/Pharmacy Regulation Process
- Discuss Board of Pharmacy Inspection Process
Who Regulates Pharmacy?

- Board of Pharmacy
- Drug Enforcement Administration (DEA)
- Food and Drug Administration (FDA)
- Consumer Products Safety Commission (CPSC)
- Centers for Medicare & Medicaid Services (CMS)
- Dept. of Social & Health Services (Medicaid)
- Dept. of Ecology
- Dept. of Labor & Industries
- Occupational Safety & Health Administration
- Joint Commission on Accreditation of Healthcare Orgs (JCAHO)
Who Regulates Drugs

- FDA
  - Initial approval
  - Manufacture/Distribution
- DEA
  - Controlled Substances
  - Mfr/dist/storage/disposal
- States
  - Board of Pharmacy Rx
  - Boards - Professionals
Centers for Medicare and Medicaid (CMS)
- Formerly Health Care Financing Admin. HCFA
- Conditions of Participation
  - Hospitals
  - Nursing Homes
  - Hospice
Who Regulates, cont.

DSHS – Medicaid
- Sets fees and rules
- Large percent of business
- Set standard for other insurers
Who Regulates, cont.

Washington State Health Care Authority
Preferred Drug List Program for State Rx Prog.
Will determine which drug in a therapeutic class may be dispensed to patients of:
- Medicaid - poverty level and below
- Labor & Industries - injured workers
- Basic Health Plan - Above poverty level
- State Employees-Uniform Medical Plan
Consumer Products Safety Commission
  - Sets requirements for Child Resistant Closures
    • (Safety caps)
    • Required on Rx unless patient or prescriber says no
Who Regulates,

- Occupational Safety and Health Admin. (OSHA)
- Workplace safety
- Including IV mixing rules
- WA Dept. Labor and Industries (L & I)
  - State affiliate of OSHA – Similar standards
  - Also pays for Rx’s for injured workers
Who Regulates

Department of Ecology

– Concerned with disposal of outdated drugs
– Current issue
  • What is hazardous waste?
  • Epinephrine, warfarin, paraldahyde, etc.
Prescribing Authority

Must be authorized under State Law

Governed by:

- Legend Drug Act
- Food Drug and Cosmetic Act
- Uniform Controlled Substances Act
- Professional Practice Acts
- Rules adopted under above laws
Drug Classifications

- **Over the Counter (OTC)**
- **Things that look like drugs (nutritional supplements & herbs)**
- **Prescription Drugs (Legend drugs)**
  - Formerly “Caution Federal law prohibits dispensing except on the prescription of a physician.”
  - Now “Rx only”
- **Controlled Substances**
  - Classified in Five Schedules according to potential for abuse and risk of addiction
  - Schedules I, II, III, IV, V
Controlled Substances Schedules

I - Heroin, marihuana, LSD, illegal substances

II - Morphine, Oxycodone (Percodan, Percocet, OxyContin) codeine, cocaine, meperidine (Demerol) Ritalin, amphetamines, secobarbital, pentobarbital,

III - Codeine combinations (Tylenol w/ Codeine) Hydrocodone combinations (Vicodin, Lortabs), Marinol

IV - Phenobarbital, benzodiazepines (Librium, Valium), Propoxyphene (Darvon), Talwin

V - Codeine cough syrups, antidiarrheals
## Prescribing Authority

<table>
<thead>
<tr>
<th>PROFESSION</th>
<th>RESTRICTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians (MD)</td>
<td>None</td>
</tr>
<tr>
<td>Physicians (DO)</td>
<td>None</td>
</tr>
<tr>
<td>Dentist (DMD or DDS)</td>
<td>Dental practice only</td>
</tr>
<tr>
<td>ARNP</td>
<td>Legend &amp; Schedule V.</td>
</tr>
<tr>
<td></td>
<td>Schedule II-IV 2005</td>
</tr>
<tr>
<td>change now independent Rx ing for these drugs</td>
<td></td>
</tr>
</tbody>
</table>
Prescribing Authority

PROFESSION

CRNA

Legend & Schedule II-V for anesthesia per order and per facility protocols

Physician Assistants (PA)

As approved by the Medical Commission

Physician Assistants Certified (PA-C)

ditto
Prescribing Authority

PROFESSION  RESTRICTION
Optometrist (OD)  Formerly - Topical eye Rx only for diagnosis or treatment (DX or TX on Rx).
(Note: Certain oral drugs were authorized in 2004)
Naturopath (ND)  Limited list of drugs controlled substances - soon
Veterinarian (DVM)  Animal treatment only
Prescribing Authority

PROFESSION                        RESTRICTION
Pharmacist (RPh)                  Initiate or modify Rx
                                   therapy under protocol
Podiatric Physician (DPM)         Foot treatment only
General Limitations on Prescribing

- No self prescribing of controlled substances
- OK BUT not good idea to Rx for family members
- Drugs must be for therapeutic purpose
- There must be valid doctor-patient relationship
- Drugs must be within scope of practice
Drug Administration Authority

PROFESSION
Licensed Midwives

RESTRICTION
Administer Rx prescribed by a physician and may use certain other drugs on own (e.g., postpartum oxytocin, vitamin K, Rho immune globulin, local anesthetics, lactated ringers solution, heparin locks, Magnesium Sulfate per protocol, epinephrine for allergic reactions)
PROFESSION: Physical Therapists

RESTRICTION: Purchase & administer Topical drugs

• Anesthetics, Silver sulfadiazine for burns, etc.

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Drug Administration Authority

<table>
<thead>
<tr>
<th>PROFESSION</th>
<th>RESTRICTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>RN</td>
<td>Prescribed drugs</td>
</tr>
<tr>
<td>LPN</td>
<td>Prescribed drugs</td>
</tr>
<tr>
<td>Respiratory Care</td>
<td>Prescribed resp. drugs</td>
</tr>
<tr>
<td>Physical Therapists</td>
<td>Prescribed topical drugs</td>
</tr>
<tr>
<td>Dental Hygienists</td>
<td>Local anesthetics top Fluoride</td>
</tr>
<tr>
<td>EMT</td>
<td>Prescribed drugs/Epi</td>
</tr>
<tr>
<td>School employees</td>
<td>Per Rx order, school policy</td>
</tr>
</tbody>
</table>
Professions that may **NOT** prescribe, administer or dispense drugs

- Acupuncturists
- Counselors
- Chiropractors
- Dietitians/Nutritionists
- Dispensing Opticians
- Lay Midwives
- Ocularists
- Occupational Therapists
- Massage Practitioners
- Psychologists
- Pharmacy Technicians
How many people have prescribing or dispensing authority in WA?

<table>
<thead>
<tr>
<th>Profession</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>20,911</td>
</tr>
<tr>
<td>DO</td>
<td>771</td>
</tr>
<tr>
<td>DDS</td>
<td>5,585</td>
</tr>
<tr>
<td>DPM</td>
<td>263</td>
</tr>
<tr>
<td>DVM</td>
<td>2,744</td>
</tr>
<tr>
<td>ARNP</td>
<td>3,412</td>
</tr>
<tr>
<td>ND</td>
<td>466</td>
</tr>
<tr>
<td>PA</td>
<td>1,647</td>
</tr>
<tr>
<td>OD</td>
<td>1,134</td>
</tr>
<tr>
<td>RPh</td>
<td>7,016</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>42,086</strong></td>
</tr>
</tbody>
</table>
How do you obtain Rx authority

The Legislature must enact or amend a law
How do you obtain Rx authority, cont.

Recent attempts to expand authority:
- Naturopaths – add more drugs plus controlled
- Optometrists – Add oral & injectable plus controlled
- Nurse practitioners – Add Schedules II-IV (successful in 2001) But had to have joint practice agreement with MD or DO (This limit was removed by legislature 2005)
- EMT – Add Epinephrine injection for anaphylaxis
How many other people have administration authority?

- RN: 65,247
- LPN: 14,247
- Lic Midwives: 97
- Dental Hyg: 4,359
- Ph Techs: 6,156
- Ph Asst: 3,108
- Ph Intern: 698
<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical Techs</td>
<td>1,507</td>
</tr>
<tr>
<td>Vet. Techs</td>
<td>930</td>
</tr>
<tr>
<td>Vet. Med Clerks</td>
<td>299</td>
</tr>
<tr>
<td>Total administration &amp; access</td>
<td>96,554</td>
</tr>
<tr>
<td>Grand total Rx, Adm &amp; access</td>
<td>138,640</td>
</tr>
</tbody>
</table>
Where are drugs used/stored

- Pharmacies (1200)
- Drug Wholesalers (80)
- Hospitals (110)
- OP Surgery Ctr (50)
- MD Offices/Clinics (10,000)
- Nursing Homes (400)
- Adult Family Homes/Boarding Homes (500)
Board of Pharmacy

Board Members
- Appointed by Governor
- Confirmation by State Senate
  - 5 Pharmacists
  - 2 Non-pharmacists
- Executive Director – RPh
- 8 Investigators – RPh
- 9 Administrative Staff
Board of Pharmacy

Duties
- License Pharmacists, Pharmacies, drug distrib.
- Inspect Pharmacies, etc
- Investigate Drug Related issues
- Enact rules
- Propose law changes to legislature
- Educate regarding drug issues
Board of Pharmacy

Inspection of Pharmacies/Wholesalers/OP Surg

- About every 18 months
- Appropriate professional practices
- Proper records
- Proper storage
- Proper control of Controlled Substances
- Outdated Drugs
Board of Pharmacy

Investigation Process

- Investigate drug law violations by ANY licensee
- Pharmacy – Rx without prescription
- Theft of CS
- Use of drugs for personal use
- Other health professionals
  - Diversion of drugs for sale or personal use
  - Forgeries, theft, substitution, records fraud, etc.
Controlling sales of pseudoephedrine used to make methamphetamine

State restrictions superceded by Federal

Improving wholesaler licensing law
  – Counterfeit drugs appearing in US drug supply
  – Working with Nat. Assn. of Boards of Pharmacy

Considering an electronic controlled substance Rx monitoring program
Summary

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- Discussed Board of Pharmacy Inspection and Investigation Process